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ATLANTA, GA 30339

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| EXAMINER |
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NGUYEN, HUONG Q

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| ART UNIT | PAPER NUMBER |
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3736

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05/27/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/505,361 | Applicant(s) KENNEDY ET AL. | |
| | Examiner HELEN NGUYEN | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This Office Action is responsive to the amendment filed 2/8/2010. Claims 1-8, 11-23, 25-36, 38-42, 44-46, and 48-50 are amended. Claims 9-10 are cancelled. **Claims 1-8 and 11-50** remain pending and under prosecution.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the electronic analyzer of **Claims 1 and 49** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1-14, 16, 18-21, and 23-50** rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga (US Pat No. 6228100) in view of Moerman et al.

5. In regard to **Claims 1, 49, and 50**, Schraga discloses a blood analyzer comprising a device body 45, 46 with a blood sampling device which has a pricking element 70, forming a complete system that can be handled as a single device, whereby the device body has a pricking position which is assigned to the working position of the pricking element for coming in contact with a skin surface of a user and a charging position designed at another location on the body of the device for charging a minimal quantity of blood coming from the previously pricked skin surface, whereby a plurality pricking elements 70, 70' can be inserted into the device and can be brought one after the other into a working position for performing multiple measurements, whereby when a pricking element is positioned in its working position, the pricking element can be inserted into the skin surface of a user which is brought into the pricking position, the pricking elements are arranged on a carrier 40 which is rotatable with respect to the body of the device

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and can be inserted together with it into the device, and by rotating the carrier the pricking elements can be brought into different working positions with respect to the body of the device, best seen in Figures 1 and 4.

6. However, Schraga does not disclose the blood analyzer comprises a plurality of testing means. Moerman et al teach an analogous blood analyzer comprising a plurality of testing means 812 used in conjunction with a plurality of pricking means 844 to effectively provide an integrated lancing and testing device, best seen in Figure 8A-F. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the blood analyzer of Schraga include a plurality of testing means as taught by Moerman et al such that the testing means is for accommodating a minimal quantity of blood, the analyzer device comprises an electronic analyzer and having a display device (Figure 8B), such that blood coming from the skin surface can be charged to a testing means by being brought in contact with the skin surface in the charging positions to effectively provide an integrated lancing and testing device.

7. Claim 2: Moerman et al disclose the pricking elements 844 and the testing means 812 are arranged on the same carrier 85, which can be handled manually.

8. Claim 3: Moerman et al disclose the carrier comprises a first carrier part 84 for the testing means 812 and a second carrier part 87 for the pricking elements 844, best seen in Figure 8A-F.

9. Claim 4: Moerman et al disclose the two carrier parts can be assembled to form a manually operable unit.

10. Claim 5: Moerman et al disclose the carrier parts can be linked together in a rotationally fixed manner.

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11. Claims 6-8: Schraga discloses the carrier 40 has a central recess within which a drive device 48 for the blood sampling device is provided.
12. Claims 9-10: Schraga in combination with Moerman et al disclose the pricking elements are arranged on the carrier in such a way that when they are in the working position, they execute a pricking movement in the radial direction with respect to the rotatability of the carrier, best seen in Figure 4 of Schraga and Figure 8 of Moerman et al.
13. Claim 11: Schraga discloses the pricking elements 70 are surrounded by a sterility barrier 72 on the carrier before execution of a pricking operation, best seen in Figure 4.
14. Claims 12-14, 16: Schraga in combination with Moerman et al disclose before execution of a pricking operation, a particular pricking element is arranged in a sleeve means 52 (Schraga), forming a cylindrical space, and is held by a plunger means 24 which is movable in the sleeve means, best seen in Figure 2.
15. Claims 18-21: Schraga in combination with Moerman et al disclose multiple recesses in the carrier in each of which is arranged a pricking element.
16. Claim 23: Schraga discloses the pricking elements 70 carry a safety cap means 72 on their free end before executing a pricking operation, best seen in Figure 4.
17. Claims 24-25: Schraga discloses the safety cap means 72 is releasable from the pricking element immediately before execution of the pricking operation and brought into a receptacle space, best seen in Figure 4 and 6.
18. Claim 26: Moerman et al disclose the test means 812 are arranged on the carrier in such a way that they are axially oriented with respect to the rotatability of the carrier, best seen in Figure 8.

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19. Claims 27-28: Schraga in combination with Moerman et al disclose the carrier 40 has a carrier part for the test means, the carrier part in particular being in the form of a ring disk, the plane of the carrier part being oriented perpendicular to the axis of rotation of the carrier.

20. Claims 29-30: Schraga discloses the charging position can be covered by a movable cover part when it is not needed, best seen in Figure 1.

21. Claim 31: Schraga discloses the drive device for the pricking element can be activated by clamping a spring means, best seen in Figure 2.

22. Claims 32-37: Schraga discloses a manually movable control element 24 is provided and is connected to the drive device for the pricking element and to the rotatable carrier 40, so that when there is a movement of the control element, the drive device for the pricking element is activated and there is a rotational movement of the carrier.

23. Claims 38-40: Schraga discloses a triggering device 35 for actuating the drive device for the pricking element can be operated by contact of the skin surface with the pricking position, best seen in Figure 2.

24. Claims 41-43: Schraga discloses a retraction mechanism 27 is provided by means of which a particular pricking element 70 can be retracted directly following the pricking operation, best seen in Figure 2.

25. Claim 44: Schraga in combination with Moerman et al disclose a safety device which allows deployment of the pricking operation only when the device is being handled properly.

26. Claim 45: Moerman et al disclose the number of test means 812 that can be handled as one unit amounts to 5 to 15, best seen in Figure 8.

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27. Claim 46: Schraga in combination with Moerman et al disclose the device has an outside contour that is essentially in the form of a circular disk.

28. Claim 47: Moerman et al disclose a time display device, best seen in Figure 8A-B.

29. Claim 48: Moerman et al disclose the housing body can be worn on the wrist of a user by means of a strip 82 that can be attached to it, best seen in Figure 8A-B.

30. **Claims 15, 17, and 22** rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga in view of Moerman et al, further in view of Charlton et al (US Pat No. 5738244).

31. Schraga in combination with Moerman et al disclose the invention above as claimed but do not disclose a film covering the sleeve means in the form on a circular shape, or used as a sterility barrier. Charlton et al teach an analogous multiple testing means comprising a circular film 64 covering the testing means for an effective sterility means, best seen in Figure 5.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the invention of Schraga and Moerman et al include a circular film to cover the sleeves as taught by Charlton et al to provide an effective sterility barrier.

Response to Arguments

32. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736